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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

STEVEN MILLER, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. GALENA BIOPHARMA, INC., MARK W. SCHWARTZ, and CHRISTOPHER S. LENTO, Defendants.	Case No.: 2:17-cv-00929-JMV-JBC SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS **JURY TRIAL DEMANDED**

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Lead Plaintiffs Dan Grunfeld, Shawn Kracht, Joseph Selinger, James Huisman, and Brooks Lieske ("Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and beliefs are based upon, among other things, Plaintiffs' counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Galena Biopharma, Inc., ("Galena" or the "Company"), with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Galena; (c) review and analysis of transcripts and exhibits from the criminal trial against Dr. Xiulu Ruan and Dr. John Patrick Couch in *USA v. Couch*, No. 1:15-cr-00088-CG-B (S.D. Ala.); (d) interviews with confidential witnesses who are former employees of Galena; and (e) review of other publicly available information concerning Galena.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that acquired Galena's securities from November 3, 2014 through January 31, 2017, inclusive (the "Class Period"), against the Defendants,[1] seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Galena is a biopharmaceutical company that develops hematology and oncology therapeutics. On October 3, 2013, the Company announced the product launch of Abstral (fentanyl). Galena manufactures and markets Abstral in the United States through its commercial organization. As explained by the Company in its SEC filings, Galena "sell[s] Abstral in the United States to wholesale pharmaceutical distributors and retail pharmacies, or our 'customers[.]'"

3. Abstral (fentanyl), a powerful opioid narcotic, is approved by the U.S. Food and Drug Administration ("FDA"), as a sublingual (under the tongue) tablet for the management of

[1] "Defendants" refers to Galena, Mark W. Schwartz, and Christopher S. Lento collectively.

breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. Abstral is a transmucosal immediate release fentanyl ("TIRF") product with product class oversight by the TIRF Risk Evaluation and Mitigation Strategy (REMS) access program implemented by the FDA.

4. During the Class Period, Galena had only two commercial products that were approved by the FDA and could be marketed and sold: Abstral and Zuplenz. However, Galena had no sales of, or revenues from, Zuplenz during the Class Period or at any time, making Abstral Galena's only revenue generating commercial product.

5. Unbeknownst to investors, throughout the Class Period, Defendants were promoting and incentivizing the Company's top two prescribers of Abstral (by significant margins) to prescribe the highly addictive medication off-label and for non-medically necessary purposes. In May 2015, these prescribers were arrested for running a "pill mill" and their practices were shut down.

6. On August 6, 2015, Galena reported sales of $3.38 million from Abstral and an operating loss of $11.3 million for the second quarter ended March 31, 2015, underperforming Wall Street projections. Additionally, Galena announced that full-year revenue from sales of Abstral would be closer to $15 million, which was the low end of the Company's beginning-of-the-year forecast of $15 million to $18 million and about $1 million below what Wall Street was projecting. On this news Galena's stock price fell $0.12, or 7.4%, from its closing price of $1.63 on August 6, 2015 to close at $1.51 on August 7, 2015.

7. Then, on November 9, 2015, Galena announced that it had decided to divest its commercial business, that is, Abstral and Zuplenz. As such, the Company's commercial business activities were classified as "discontinued operations," and Galena stated that it anticipated exiting the commercial business by the end of the first quarter of 2016. Galena also reported an $8.1 million

impairment charge to its commercial business net asset group. On this news, the price of Galena common stock fell $0.19 per share, or 11%, to close at $1.53 per share on November 10, 2015.

8. On December 22, 2015, the Company announced that it received a subpoena from the U.S. Attorney's Office for the District of New Jersey requesting the production of a broad range of documents pertaining to marketing and promotional practices related to Abstral. On this news, the price of Galena common stock fell $0.06 per share, or 3.6%, to close at $1.57 per share on December 23, 2015.

9. On March 10, 2016, the Company disclosed that "[a] federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes," and that the Company had received a trial subpoena in connection with that investigation and had been in contact with the U.S. Attorney's Office for the Southern District of Alabama, which was handling the criminal trial. The Company further stated that "other governmental agencies may be investigating our Abstral promotion practices," and that "on December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral." On this news, the price of Galena common stock fell $0.03 per share, or 3.3%, to close at $0.86 per share on March 11, 2016.

10. Then, on May 10, 2016, Galena announced that on April 28, 2016, a second superseding indictment was filed in the criminal case against the two doctors in Alabama, "which added additional information about the defendant physicians and provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock" and that "we have learned that the

FDA and other governmental agencies may be investigating our Abstral promotion practices." On this news, Galena's stock price fell $0.10, or 7.2%, to close at $1.38 on May 11, 2016.

11. On January 9, 2017, the Company filed a Form 8-K with the SEC. Therein, the Company disclosed that the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and the Department of Justice was a criminal investigation in addition to a civil investigation that could ultimately involve the Company as well as one or more current and/or former employees, that it was reimbursing any former and current employees' attorney's fees with respect to the investigation, and that the FDA and other government agencies were indeed investigating the Company's Abstral promotional practices.

12. On this news, the price of Galena common stock fell $0.04 per share, or 1.9%, to close at $2.03 per share on January 9, 2017.[2]

13. The Class Period closes on January 31, 2017. On that date, the Company announced the resignation of Defendant Mark W. Schwartz as President, Chief Executive Officer ("CEO"), and a member of the Board of Directors and that the Company was "in the process of engaging an independent advisory firm to evaluate strategic alternatives for the company." News outlets tied Schwartz's abrupt resignation to the federal investigation of Galena's marketing and promotional practices for Abstral.

14. On this news, the price of Galena common stock fell $0.37 per share, or 22.4%, to close at $1.28 per share on February 1, 2017. The stock price continued to decline, falling another $0.16 per share, or 12.5%, to close at $1.12 on February 2, 2017.

15. Following the close of the Class Period, news concerning Galena's Abstral promotional practices, and the federal investigation of those promotional practices, continued to

[2] The Company executed a 1-for-20 reverse stock split on November 11, 2016. All prices after that date in this complaint are the post-split prices.

trickle out, including from periodic reports concerning the criminal trial and sentencing of the two high-prescribing Abstral doctors.

16. On September 8, 2017, after the close of the Class Period, the United States Department of Justice ("DOJ") announced that it reached an agreement with Galena "to resolve allegations that [Galena] paid kickbacks to doctors to induce them to prescribe its fentanyl-based drug Abstral."[3] The settlement resolves a lawsuit filed by a whistleblower under the False Claims Act, which permits private parties to file suit on behalf of the United States and obtain a portion of the government's recovery. As part of the settlement Galena agreed to pay $7.55 million. The DOJ press release stated: '"The conduct alleged by the government and resolved by today's settlement was ***egregious because it incentivized doctors to over-prescribe highly addictive opioids***,' Acting U.S. Attorney Fitzpatrick said." No other information about the government's investigation of, or lawsuits against, Galena was disclosed due to the fact that "the matter remains under seal as to allegations against entities other than Galena."

17. Plaintiffs allege that during the Class Period, Defendants materially misled the investing public concerning the value of Galena's securities. Specifically, Defendants issued materially false or misleading statements that touted the Company's increased Abstral revenues while attributing those revenues to legitimate and legal promotions of Abstral. In truth, however: (1) the Company's revenues were the result of illegal and unsustainable promotional practices, including illegal kickbacks; (2) Galena's net sales and revenues were reliant on illegal, non-medically

[3] By the time of the DOJ press release, the Company had announced its agreement to complete a reverse merger, wherein Galena was to be acquired by Sellas Life Sciences. The agreement on the reverse merger was finalized on August 8, 2017. As reported by a biopharmaceutical analyst: "The reverse merger with Sellas could breathe new life into Galena, which has had a disappointing year. In March, the company announced it was looking for a company to acquire its holdings, two months after its CEO Mark W. Schwartz quit amid a federal investigation into the company's marketing strategy for its opioid Abstral (fentanyl)." *See* https://www.pharmalive.com/bay-area-galena-biopharma-merges-with-oncology-focused-biopharma-in-all-stock-deal/.

necessary prescriptions of Abstral by at least two disreputable pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks; (3) the Company violated various federal statutes in connection with its sales of Abstral; and (4) that, as such, the Company's revenues were overstated and Galena was exposed to civil and criminal liability.

18. As the concealed risks of Galena's illegal promotional practices materialized—*i.e.*, when the two over-prescribing doctors' practices were shut down and Abstral sales dropped off, and when the federal government opened investigations into Galena's Abstral promotional practices—and were revealed through a series of disclosures made by Galena, as set forth above (and further herein), the artificial inflation in Galena stock dissipated and investors suffered significant damages.

II. JURISDICTION AND VENUE

19. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

21. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

22. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the

United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

23. Plaintiff Dan Grunfeld, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

24. Plaintiff Shawn Kracht, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

25. Plaintiff Joseph Selinger, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

26. Plaintiff James Huisman, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

27. Plaintiff Brooks Lieske, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

28. Defendant Galena Biopharma, Inc. is a Delaware corporation headquartered in San Ramon, California. Galena's common stock trades on the NASDAQ Stock Market ("NASDAQ") under the symbol "GALE."

29. Defendant Mark W. Schwartz ("Schwartz") was the President, and CEO of Galena from August 20, 2014, through the end of the Class Period. From 2011 until his appointment as CEO, Defendant Schwartz served as Executive Vice President and Chief Operating Officer ("COO") for Galena.

30. Defendant Christopher S. Lento ("Lento") was the Senior Vice President of Oncology Commercial Operations at Galena from around May 2013 through December 31, 2015.

31. Defendants Schwartz and Lento, (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of Galena's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers, and investors. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

A. Background of Galena and Its Highly Addictive Drug, Abstral

32. On October 3, 2013, the Company announced the product launch of Abstral (fentanyl) sublingual tablets, a drug designed to address breakthrough cancer pain.

33. Abstral (fentanyl) is an opioid pain medication that is associated with a high risk of addiction and dependence. Fentanyl is reportedly fifty times more potent than heroin and up to 100 times stronger than morphine, making it the most powerful and potentially lethal opioid pain medication available. Fentanyl is among the medications at the epicenter of the growing opioid epidemic in the United States, which has attracted the attention of United States regulators and other public officials, including former President Barrack Obama and current President Donald Trump.

34. Fentanyl is a major contributor to the alarming number of opioid overdose deaths currently plaguing the nation. For example, as reported in a May 14, 2016 Wall Street Journal article entitled "Hooked: One Family's Ordeal With Fentanyl," in twelve states particularly affected by the opioid epidemic, including New Hampshire, Massachusetts, and Ohio, more than 5,500 people died of fentanyl-related overdoses between 2013 and 2015.

35. Abstral is specifically indicated by the FDA ***only*** for "the management of breakthrough pain in ***cancer*** patients 18 years of age and older ***who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain***." Prescriptions written to patients that do not fit this criteria are considered off-label.

B. Legal and Regulatory Framework Governing Sales and Marketing of Abstral

1. FDA Regulations on Off-Label Marketing

36. Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, 21 U.S.C. § 301, *et seq.*, a drug manufacturer, such as Galena, is prohibited from distributing drugs in interstate commerce for any intended use that the FDA has not approved as safe and effective. 21 U.S.C. § 355 (a) and (b).

37. To obtain authorization from the FDA to sell a new drug product, a company must first submit and receive the FDA's approval of a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355. In the NDA, the company must describe all intended uses proposed for a new drug's

labeling and prove that the new drug is safe and effective for those uses based upon data from its clinical trials. 21 U.S.C. § 355 (b).

38. The FDA determines whether a medical product is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling submitted to the FDA with the product's marketing application or submission. In making this determination, the FDA evaluates whether the conditions of use in the proposed labeling are supported by the required levels and types of evidence of safety and effectiveness and whether the benefits of using the product under those specific conditions of use outweigh the risks of the product. After the FDA approves or clears a medical product, the FDA-required labeling sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing, and it provides directions and information on how to use the product safely and effectively under those conditions. *Guidance for Industry, (Draft Guidance), Medical Product Communication That Are Consistent With the FDA-Required Labeling – Questions and Answers,* at 2 (Background).

39. When the FDA reviews an NDA and approves a drug for commercialization, such approval is only with respect to the intended use(s) proposed in the NDA and approved for the drug's labeling. In other words, "[a] use that does not appear in the labeling is not approved as safe and effective by FDA and is known as an 'unapproved' or 'off-label' use." 65 Fed. Reg. 14286-01.

40. When a company promotes an approved drug for an off-label use, the drug becomes an unapproved "new drug" with respect to that use. *See* 21 U.S.C. § 355 (a), (b), (d), (j). In addition, the approved drug is considered "misbranded" because the labeling of such a drug would not include "adequate directions for use" under 21 U.S.C. § 352 (f). Both unapproved new drugs and misbranded drugs are prohibited from distribution in interstate commerce. *See* 21 U.S.C. 331 (a), (d), (k). Accordingly, ***off-label marketing violates the FDCA***.

41. The FDA-approved product label for Abstral states that the drug is "indicated for the management of breakthrough pain in ***cancer*** patients 18 years of age and older ***who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain***."

42. It is illegal for drug companies to promote the off-label use of pharmaceuticals. Similarly, while doctors are permitted to prescribe a pharmaceutical for a legitimate medical off-label purpose, it is illegal for doctors to prescribe a controlled substance for non-medically necessary purposes.

2. Federal Anti-Kickback Provisions

43. In addition to FDA regulations, Galena's marketing practices are subject to federal anti-kickback laws, which prohibit, among other misconduct, offering, paying, or soliciting remuneration to induce the purchasing or ordering (or arranging for the purchase or ordering of) any healthcare item, such as a drug, reimbursable under any federally financed healthcare program, such as Medicare and Medicaid.

44. Specifically, under the Anti-Kickback Statute, ***it is illegal for an individual to knowingly and willfully offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program***. *See* 42 U.S.C. § 1320a-7(b)(2). "Remuneration" refers broadly to anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. *See* Department of Health and Human Services, Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003).

45. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure ***proper*** medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thus interfering with the patient's right to choose proper medical care and services. *See* Medicare and

Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 309 (proposed Jan. 23, 1989) (codified at 42 C.F.R. pt. 1001).

3. Government's Strict Enforcement of Laws Regulating Pharmaceutical Companies

46. The U.S. government strictly enforces laws that regulate the practices of pharmaceutical companies in their manufacturing and distribution of controlled substances. Such stringent enforcement is necessary in order to counterbalance the monetary incentives that can drive pharmaceutical companies to use aggressive and unethical tactics to increase sales of dangerous drugs. As such, the U.S. Department of Justice, and state attorneys general, have repeatedly taken legal action against pharmaceutical companies that violate applicable laws. For example, on November 4, 2013, the DOJ issued a press release entitled, "Johnson & Johnson to Pay More than $2.2 Billion to Resolve Criminal and Civil Investigations: Allegations Include Off-Label Marketing and Kickbacks to Doctors and Pharmacists."[4] Coincidentally, the issuance of this DOJ press release on November 4, 2013 came just as Defendants were beginning to engage in similarly unlawful conduct, as described below.

C. Defendants Illegally Promoted Abstral and Utilized Disreputable Doctors to Artificially Inflate Abstral Sales and Revenues

1. Galena's Abstral Sales Were Propped Up By Two Doctors Illegally Prescribing Abstral For Non-Medically Necessary Purposes

47. More than ***thirty percent*** of Galena's Abstral sales were generated by just two pain management doctors, Dr. Xiulu Ruan and Dr. John Patrick Couch, who were convicted of running a pill mill in Mobile, Alabama.[5] The facts alleged in the below paragraphs in this section came directly from information provided by the United States Department of Justice in public releases.

[4] The press release is available at: https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations.

[5] Another 10% was generated by Dr. Rho, also a pain management doctor and a "good friend" of Dr. Ruan.

48. Dr. Ruan and Dr. Couch jointly owned and operated two pain management clinics under the name Physicians Pain Specialists of Alabama ("PPSA") as well as C&R Pharmacy, which was co-located with one of the PPSA clinic locations. C&R Pharmacy would only fill prescriptions written by the doctors at PPSA, and Dr. Ruan and Dr. Couch split 75% of the profits that came in from the prescription drug reimbursements. According to the DOJ, approximately 91% of the Abstral prescriptions written by Drs. Ruan and Couch—which cost their patients' insurance anywhere between $1,000 to $24,000 per month—were filled at C&R Pharmacy.

49. PPSA's clinics were raided by law enforcement on May 20, 2015, following an extensive joint investigation by the FBI and DEA. Both doctors were charged with a litany of federal felony offenses, including RICO conspiracy, conspiracy to violate the Controlled Substances Act, substantive drug distribution offenses, conspiracies to commit wire fraud, mail fraud, healthcare fraud, and to violate the federal Anti-Kickback Statute, as well as money laundering. All charges stemmed from the doctors' operation of PPSA and C&R Pharmacy. While no charges were brought against Drs. Ruan or Couch specifically for their relationship with Galena, both doctors were charged with, among others: (1) prescribing controlled substances, including Galena's drug Abstral, "based on their own financial interests, rather than the legitimate medical needs of the patients" (*see* Second Superseding Indictment at 15, attached hereto as Exhibit 6); (2) distributing and dispensing fentanyl, including Galena's drug Abstral, "outside the usual course of professional medical practice and not for a legitimate medical purpose" (*id.* at 21); (3) distributing controlled substances, including Galena's Abstral, "for no legitimate medical purpose and outside the usual course of professional practice" (*id.* at 23).[6]

[6] While the Indictment included, as Count Eighteen, charges related to Drs. Ruan and Couch's relationship with Galena, this Count was later dropped and was not presented to the jury. The dismissal of this Count may have been in exchange for Galena' cooperation with the prosecution—cooperation that was discussed in a DOJ press release. *See infra* ¶53.

50. During a criminal trial, which lasted from early January to late February 2017, the United States presented evidence that Dr. Ruan and Dr. Couch utilized PPSA and C&R Pharmacy to knowingly and willfully prescribed Schedule II and III Controlled Substances, including fentanyl (with brand names including Abstral), ***outside the usual course of professional practice and not for a legitimate medical purpose***. Of particular importance in the trial were two brand name instant-release fentanyl drugs — Abstral and Subsys. Both Abstral and Subsys are only FDA-indicated for breakthrough cancer pain in opioid-tolerant adult patients. However, evidence showed that Dr. Ruan and Dr. Couch exclusively, or nearly exclusively, prescribed these drugs off-label for neck, back, and joint pain. The United States argued Drs. Ruan and Couch's motives for this illegal prescribing were their own financial self-interests.

51. With regard to Abstral, evidence showed that Drs. Ruan and Couch received illegal kickbacks from Galena in exchange for the doctors' prescribing the drug off-label to non-cancer patients. The evidence also showed that Dr. Ruan and Dr. Couch purchased more than $1.6 million worth of stock in Galena, the manufacturer of Abstral, and sought to manipulate the stock price by driving up Abstral sales. From the third quarter of 2013 through at least the end of 2014, Dr. Ruan and Dr. Couch were the number one and two prescribers of Abstral in the entire United States, prescribing inordinately large amounts of Abstral that far exceeded the prescriptions written by other doctors. During this same time period, ***nearly one out of every three*** Abstral prescriptions written in the U.S. were written by either Dr. Ruan or Dr. Couch for off-label purposes.

52. After seven weeks of trial, the jury ***convicted*** both doctors of several counts, including conspiracy to prescribe Schedule II and III Controlled Substances outside the usual course of professional practice, conspiracy to prescribe more than 40 grams of fentanyl (***including Abstral***) outside the usual course of professional practice, conspiracy to commit healthcare fraud, and several substantive illegal drug distribution counts related to prescriptions written to particular patients. *See*

Verdicts, attached hereto as Exhibit 7 (showing that both doctors were convicted on Counts One, Three, and Eight, which specifically related to the doctors' prescriptions of Abstral).[7] Dr. Ruan and Dr. Couch were sentenced to 252 months and 240 months, respectively.

53. During this time, the DOJ and DNJ had instituted a civil and criminal investigation ***into Galena*** for illegal kickbacks Galena paid to doctors, including Drs. Ruan and Couch, in violation of the Anti-Kickback Statute and False Claims Act. As disclosed in a press release issued by the DOJ on September 8, 2017, the action was settled in exchange for Galena paying more than $7.55 million to the government. The DOJ's September 8, 2017 press release read, in pertinent part, as follows:

> Galena Biopharma Inc. (Galena) will pay more than $7.55 million to resolve allegations under the civil False Claims Act that ***it paid kickbacks to doctors to induce them to prescribe its fentanyl-based drug Abstral***, the Department of Justice announced today.
>
> "Given the dangers associated with opioids such as Abstral, it is imperative that prescriptions be based on a patient's medical need rather than a doctor's financial interests," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "The Department of Justice intends to vigorously pursue those who offer and receive illegal inducements that undermine the integrity of government health care programs."
>
> "The conduct alleged by the government and resolved by today's settlement was egregious because it incentivized doctors to over-prescribe highly addictive opioids," said Acting U.S. Attorney William E. Fitzpatrick for the District of New Jersey. "This settlement constitutes another example of the Department of Justice's ongoing efforts to battle the opioid epidemic on every front."
>
> The United States contends that ***Galena paid multiple types of kickbacks to induce doctors to prescribe Abstral***, including providing more than 85 free meals to doctors and staff from a single, high-prescribing practice; paying doctors $5,000, and speakers $6,000, plus expenses, to attend an "advisory board" that was partly planned, and attended, by Galena sales team members and paying approximately $92,000 to a physician-owned pharmacy under a ***performance-based rebate agreement to induce the owners to prescribe Abstral.*** The United States also contends that ***Galena paid doctors to refer patients to the company's RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but***

[7] In addition, both doctors were convicted of conspiracy to commit mail and wire fraud, and Dr. Ruan was convicted of both conspiracy and substantive money laundering counts.

> ***acted as a means to induce the doctors to prescribe Abstral.*** Galena has not marketed any pharmaceutical drug since the end of 2015.
>
> Two of the doctors who received remuneration from Galena were tried, convicted and later sentenced to prison in the U.S. District Court for the Southern District of Alabama following a jury trial of, among other counts, ***offenses relating to their prescriptions of Abstral. Galena cooperated in that prosecution***.
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> ***
>
> The settlement is the result of a coordinated effort by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the District of New Jersey, with assistance from the Department of Health and Human Services Office of Counsel to the Inspector General, and the Food and Drug Administration Office of Criminal Investigations' Metro Washington Field Office.
>
> [Emphasis added.]

54. The DOJ also brought charges against former officers of Insys Therapeutics, Inc., the manufacturer of Subsys, for illegal kickbacks the company paid to doctors in exchange for writing prescriptions of Subsys.

2. Evidence Presented During the Criminal Trial Against Drs. Ruan and Couch Demonstrate that Defendants Knowingly Paid Illegal Kickbacks to Doctors and Promoted Abstral for Off-Label Purposes

55. Evidence presented during the criminal trial against Drs. Ruan and Couch demonstrates that throughout the Class Period, Defendants knowingly encouraged and promoted Abstral for use in non-cancer patients even though Abstral was not approved for that purpose. In particular, based on the emails between Dr. Ruan and Defendants Lento and Schwartz, ***since at least October 2013, Defendant Schwartz and Defendant Lento knew*** that PPSA treated few, if any, cancer patients. *Id.* However, despite being specifically told by Dr. Ruan in October 2013 that PPSA did not have cancer patients with breakthrough cancer pain, Defendants Lento and Schwartz continued to promote Abstral to Drs. Ruan and Couch and pushed the doctors to prescribe Abstral to their non-cancer PPSA patients. Defendants' promotions of Abstral included paying Drs. Ruan and Couch for their Abstral prescriptions to patients that Defendants knew were non-cancer patients.

Such promotions constituted ***both*** illegal kickbacks and illegal off-label promoting by, and on behalf of, Galena.

a. Galena'a "RELIEF" Registry

56. According to evidence and testimony presented at the criminal trial of Drs. Ruan and Couch, Galena created and maintained a "RELIEF" registry/program that Galena launched in July 31, 2013. According to Galena's "fact sheet" for the registry, the name RELIEF stands for "Rapid Evaluation of Lifestyle, Independence, and Elimination of Breakthrough Cancer Pain with Freedom." *See* Exhibit 2 (attached hereto). The program was purportedly designed to be an "[o]bservational patient registry study as indicated for the management of breakthrough pain (BTcP) in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." *Id.* Conveniently, the program also paid doctors $500 for every Abstral patient the doctors enrolled in the RELIEF registry. *On paper*, the RELIEF program was only available to a "patient prescribed Abstral ***for BTcP*** [breakthrough cancer pain]."[8] *Id.* Importantly, however, David Corin ("Corin") (Galena's National Sales Director) unequivocally testified that *in application*, Galena knowingly used the RELIEF program for prescriptions to treat non-cancer pain in patients who did not even have cancer. Indeed, Mr. Corin's sworn testimony is clear:

Q: Who were the patients that could qualify for the RELIEF Program?

A: Cancer and ***noncancer*** patients.

57. Thus, Galena ***knowingly*** paid doctors for their prescriptions to, and enrollments of, ***non-cancer patients*** via the RELIEF program. By implementing and maintaining a program that

[8] While the term BTcP is used in Galena's literature, the abbreviation BTcP to stand for breakthrough cancer pain is well known in the industry. *See e.g.* https://www.ncbi.nlm.nih.gov/pubmed/29875184.

knowingly paid doctors for their Abstral prescriptions to non-cancer patients, Galena was promoting the drug for off-label purposes and providing illegal kickbacks.

58. Moreover, ***Defendants Lento and Schwartz*** knew that the RELIEF program was operating to pay doctors for Abstral prescriptions, including prescriptions to non-cancer patients.

59. According to emails from October 2013 between ***Defendant Lento*** and Dr. Ruan—emails that were copied to ***Defendant Schwartz***, Allan Valmonte (Galena's Director of Clinical Affairs), and David Rowan (Galena's Regional Business Director)—***Defendant Lento*** promoted the RELIEF program for non-cancer patients and ***encouraged*** Dr. Ruan ***to enroll PPSA's non-cancer patients in Galena's "RELIEF" program***. *See* Exhibit 3 (attached hereto). Indeed, the emails reflect that Galena's sales representative Jeff Palmer had pitched the RELIEF program to Dr. Ruan and that Dr. Ruan had expressed "interest" in the program; however, when Dr. Ruan was sent the information for the RELIEF program, he did not think he had qualifying patients—because the documentation suggested that it applied only to cancer patients with breakthrough cancer pain. *See id.*[9] (explaining that Dr. Ruan initially "was under the impression that the candidates for the study would be patients with non-malignant pain" but he later thought (after reviewing the documentation) that the RELIEF program only applied to cancer patients for which his "practice does ***not*** have very many patients who qualify," *i.e.*, does not have many cancer patients). *See id.* In his sworn testimony, Corin confirmed that Dr. Ruan's stated reason for not participating in the RELIEF program was that Dr. Ruan said ***"he doesn't have many cancer pain patients***, explaining that Dr. Ruan's reference to non-malignant pain meant "noncancer pain."

60. In response to the email explaining that Dr. Ruan did not think he had patients that could participate in the RELIEF program, ***Defendant Lento,*** coping and invoking ***Defendant***

[9] The emails reflect that Galena was partially working through Sunbelt Research Group, LLC, to get Dr. Ruan to participate in the RELIEF program. Research indicates that Sunbelt Research Group, LLC is/was classified as a "pharmaceutical preparations company."

Schwartz, corrected Dr. Ruan and tried to persuade Dr. Ruan to prescribe Abstral to his non-cancer patients and to enroll those non-cancer patients in the RELIEF program, saying:

> I hope all is well. I was surprised to receive this note today (via Neil). ***I had thought that you were very excited to participate in Galena's RELIEF Registry***. ***I believe there might exist some confusion on patient eligibility***. Would it be possible to discuss at your earliest convenience?
>
> ***I'm copying Mark Schwartz***, (Galena COO), and Allan Valmonte, (Director of Clinical Affairs), and Dave Corin (Regional Business Director).
>
> Thank you for your consideration.

Exhibit 3 at p. 1 (emphasis added). Indeed, as David Corin testified, Dr. Ruan misunderstood the program's eligibility because Galena's RELIEF program actually enrolled both "cancer ***and non-cancer patients***."

61. While Dr. Ruan ultimately chose not to participate in Galena's RELIEF program (out of concern that he would not be able to freely trade his Galena stock), Dr. Couch ***did*** participate in Galena's RELIEF program and received several payments from Galena for his Abstral prescriptions to non-cancer patients. In fact, while Galena's RELIEF program was originally designed to have a limit so that a doctor could only enroll a maximum of 25 patients on the RELIEF program, "the ***parameters were changed where Dr. Couch was allowed to enroll up to 75 patients***" in the RELIEF program, according to David Corin's testimony. In addition, David Corin testified that while the RELIEF program was also originally designed to pay the doctor $500 per patient, Dr. Couch was allowed to request payment of "***up to $2,500 per patient***." Thus, Defendants not only allowed Dr. Couch to enroll his non-cancer patients in the RELIEF program but even changed the program's parameters to allow Dr. Couch to enroll even more non-cancer patients in the program and for apparently higher payments.

62. Defendants' application of Galena's RELIEF program was illegal in two ways: (1) it constituted off-label promotion of a drug for an unindicated purpose, in violation of the FDCA; and

(2) it provided doctors with illegal kickbacks for their prescriptions of Abstral, in violation of the Anti-Kickback Statute. Indeed, the RELIEF program paid doctors for their prescriptions of Abstral—a clear kickback. Unsurprisingly then, in the DOJ press release announcing its settlement with Galena, the DOJ and DNJ specifically took aim at the RELIEF program, describing it as a kickback, saying: "Galena paid doctors to refer patients to the company's RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral."

b. Galena's Rebate Agreement

63. David Corin (Galena's National Sales Director) testified that Galena had rebate agreements with several dispensing clinics. According to Corin, under the rebate agreements, Galena was to pay the dispensing clinics a percentage, generally ranging from 8.75% to 20%, of the prescription dollars the clinic/pharmacy sold in a given month.[10] This, again, is a classic example of a kickback.

64. On October 1, 2014, Galena entered into such a rebate agreement with C&R pharmacy, the pharmacy owned by Drs. Couch and Ruan. As Corin testified, in 2014, "the company and C&R Pharmacy [Dr. Couch and Dr. Ruan's pharmacy] partnered on a marketing services agreement," which was "also known as the rebate agreement." The prosecution entered the marketing services/rebate agreement into evidence, and as Corin testified, the rebate agreement was signed by ***Defendant Schwartz*** on behalf of Galena and was executed on October 1, 2014. *See* attached hereto Exhibit 4 (rebate agreement). Under the rebate agreement, Galena would pay C&R Pharmacy a certain percentage, between 8.75% and 20%, for the prescriptions of Abstral the pharmacy sold in a month. Corin said that he was aware that Drs. Couch and Ruan owned C&R

[10] Indeed, Mr. Corin, explained that the rebate agreements would essentially be the same as the one Galena entered into with C&R pharmacy: "the only difference is it's C&R."

Pharmacy. As Justin Palmer (nurse practitioner at PPSA) testified, "C&R [the pharmacy owned by Drs. Couch and Ruan] was part of PPSA, at least in my mind, and it was connected to the building." Mr. Palmer further testified that the PPSA patients essentially always got their Abstral prescriptions filled at C&R Pharmacy, which was connected to the PPSA clinic, due to the fact that Abstral "was such an expensive drug, that nobody else really carried it and we did."

65. As Corin explained, "[t]he average prescription [of Abstral] could be several thousand dollars. For the higher doses, you can get into the $10,000 range." Press releases from the DOJ have similarly explained that Abstral costs a patients' insurance anywhere from $1,000.00 to $24,000.00 per month. Accordingly, the 8.75% to 20% kickback available to C&R, pursuant to the rebate agreement, was a significant incentive to Drs. Ruan and Couch to write more prescriptions of Abstral (regardless of medical need).

66. Corin testified that "when this agreement went into place, C&R Pharmacy would earn more money from filling Abstral prescriptions." And the rebate agreement ***did*** provide more money to Drs. Ruan and Couch, as evidenced by a Federal Reserve document that the prosecution entered into evidence, which reflected a February 18, 2015 wire in the amount of ***$97,924*** from Galena to C&R Pharmacy's Wells Fargo bank account. FBI agent Amy White testified that the FBI believed the $97,924 wire to be a payment pursuant to the rebate agreement.

67. Corin testified that the rebate agreement was, in fact, made "in order to add additional profit to C&R's prescrib[ing] or dispensing of Abstral." In other words, Galena entered into the rebate agreement with C&R Pharmacy to incentivize Drs. Couch and Ruan to write more prescriptions for Abstral and to write those prescriptions to patients Defendants then-knew to be non-cancer patients.

68. Specifically, the testimony of David Corin indicates that Galena entered into the rebate agreement with the doctors in order to increase Drs. Ruan and Couch's Abstral prescriptions

following a drop in the doctors' prescription rate. Indeed, while Drs. Ruan and Couch were consistently the top prescribers of Abstral, the number of prescriptions Drs. Ruan and Couch wrote had decreased beginning in early 2014. According to Corin, Galena largely attributed the decreased prescriptions[11] to a change to how the Company's voucher program was applied to Drs. Ruan and Couch:

> Q: What, if anything, did Galena Biopharma attribute the dropoff in Dr. Ruan and Dr. Couch to during that time period, from quarter one to quarter two?
>
> A: The change in rules that we put into the voucher program.
>
> Q: And by and large, as you reviewed this document [attached hereto as Exhibit 5] previously, did you see similar massive drop-offs for a lot of other doctors from first to second quarter?
>
> A: No.

69. According to testimony from David Corin, since the time Galena began marketing Abstral, it had a voucher program that permitted new Abstral patients to receive certain initial prescriptions of Abstral for free. Corin testified that Galena's voucher program allowed new Abstral patients to "get up to three prescriptions of Abstral at 32 tablets apiece, so up to 96 tablets of Abstral free of charge while that patient worked to get to the right dosage to treat their cancer pain." Conveniently, the voucher program also paid the pharmacy that filled the prescription 8.75 percent of the prescription amount as a "service fee." As Corin testified, "[s]o we pay the pharmacy 8.75 percent for a voucher to initiate the patient." Corin explained that for non-voucher "maintenance" prescriptions (*i.e.*, prescriptions for patients already taking Abstral), the pharmacy would ***not*** receive the 8.75 percent "service fee."

[11] Mr. Corin also testified that the dropoff in Abstral prescriptions from Drs. Ruan and Couch coincided with an insider trading scandal at Galena that was made public in or around February 2014 and which upset Drs. Ruan and Couch because it negatively affected their Galena stock holdings.

70. As Corin also testified, Galena initially permitted Dr. Ruan and Couch to use all three vouchers (for a total of 96 tablets of Abstral) at once, but Galena stopped allowing this in March 2014. As Corin testified:

> Q: Did Dr. Ruan and Dr. Couch abide by the way the voucher program was supposed to work?
>
> A: ***They -- they used it differently***.
>
> Q: How did they -- how did Dr. Ruan and Dr. Couch use the voucher program?
>
> A: ***All three prescriptions would be written at once.***
>
> Q: Why is that different than what you described as the way it was supposed to work?
>
> A: Because the titration model didn't fall into place, so the dose was pre-selected for all three prescriptions.
>
> ***
>
> Q: Was there a change – you mentioned that a change was made to the voucher program?
>
> A: Yes.
>
> Q: When was that change made?
>
> A: In March of 2014.
>
> Q: Why was that change made?
>
> A: ***Because we were losing money on the voucher program***.

71. Following the March 2014 change to Galena's voucher program, Drs. Ruan and Couch "couldn't write three vouchers at once," according to Corin:

> Q: When the voucher program changed, did it affect the way that pharmacies were reimbursed for Abstral?
>
> A: For the voucher fee?
>
> Q: Yes.

A: Well, it would only affect it in that they couldn't write three vouchers at one.

Q: ***And is that what Dr. Ruan and Dr. Couch had been doing at that time?***

A: ***Yes, for the most part.***

In other words, after March 2014, Drs. Ruan and Couch could not as readily access the 8.75 percent "service fee" that C&R had been receiving under the voucher program.

72. Thus, the rebate agreement was executed with Dr. Ruan and Couch's C&R Pharmacy to get Drs. Ruan and Couch's prescriptions back up following the change to how Galena permitted C&R to use its Abstral vouchers. Indeed, Corin testified that he made a trip to Mobile on September 24, 2014 to visit with Drs. Ruan and Couch to try to come to an arrangement with Drs. Ruan and Couch. As Corin testified:

Q: What was the purpose of this trip?

A: Again, ***Dr. Ruan was very upset with the company and wanted to understand – although he was upset, wanted to find ways to work with the company too***.

***

Q: What, if anything, did Dr. Ruan suggest be done during this meeting?

A: He suggested that the company work with the pharmacy to find a better way to procure Abstral.

Q: And when you say "work with the pharmacy," which pharmacy are you talking about?

A: C&R.

Q: And procure Abstral, what do you mean work with C&R for a better way to procure Abstral?

A: The concern was that the pharmacy was currently losing money prescribing the product for maintenance scripts.

Q: And are the maintenance scripts, are those the full-month scripts, not voucher scripts?

A: Yes. Yes.

Q: ***What, if anything, did Dr. Ruan suggest be done?***

A: ***He suggested that the company talk to the pharmacy and the -- and to find a way to partner up.***

Q: And by "partner up" what do you mean?

A: Find a way to make sure the pharmacy wasn't losing money.

73. The solution was the rebate agreement, which was signed days later. The rebate agreement achieved its intended purpose of driving up Abstral prescriptions and Galena revenues, as Mr. Corin admitted that the number of prescriptions for Abstral from Dr. Ruan and Dr. Couch increased after the rebate agreement went into effect:

A: It went into place right here and around October 1st, 2014.

Q: After that time period, after it went into place, do you know from working at Galena whether or not prescriptions form Abstral from Dr. Ruan and Dr. Couch increased?

A: ***They did increase***.

74. This increase was reflected in an internal Galena document emailed on February 5, 2015 by David Corin to Galena sales representatives, including a confidential witness ("CW") who was a Territory Business Manager for Galena from August 2014 through August 2015.[12] The document emailed by Corin, and copied to ***Defendant Lento***, on February 5, 2015 shows that the amount of Abstral prescriptions written by Drs. Ruan and Couch notably increased after the rebate agreement was executed, in the following material numbers:

	Aug. 2014	Sept. 2014	Oct. 2014	Nov. 2014	Dec. 2014	Jan. 2015
Dr. Ruan	$101,172	$147,421	**$150,683**	**$245,783**	**$230,887**	**$163,638**
Dr. Couch	$96,590	$98,706	**$188,934**	**$228,631**	**$212,827**	**$157,064**

[12] The internal Galena document was provided to Plaintiffs' Counsel by CW.

75. Thus, in comparing the two months ***before*** the rebate agreement and the two months ***after*** the rebate agreement, we see that Dr. Ruan wrote a total of $248,593 (for August and September) versus a total of $476,670 (for November and December), and Dr. Couch wrote a total of $195,296 (for August and September) versus a total of $441,458 (for November and December). *See also* Exhibit 5 (chart of Drs. Ruan and Couch's Abstral prescriptions showing a significant uptick in prescriptions around October 2014).[13] Accordingly, the rebate agreement had a material impact to Galena, particularly since the Company's total previous ***quarterly*** revenues were in the range of around $1 million to $2.3 million. *See infra*. ¶¶96, 99, 102 (comparing net revenues to the previous year's revenues). Indeed, based on the above information, Dr. Ruan's prescriptions created $627,353 in revenue for the fourth quarter of 2014, and Dr. Couch's prescriptions created $630,392 in revenue for the fourth quarter of 2014, making a combined total of ***$1,257,745*** in revenue for 2014 Q4 just from these two doctors. That amounts to ***more than half*** of any quarterly revenue the Company had reported by this time.

76. Moreover, Drs. Ruan and Couch's prescriptions under the rebate agreement ***were being paid for***, unlike the prescriptions they had written under the voucher program (which, according to Corin, made up the majority of Drs. Ruan and Couch's prescriptions prior to March 2014), for which Galena had to provide free of charge. As such, Drs. Ruan and Couch post-rebate agreement prescriptions created significantly more revenue for Galena. Indeed, Galena announced its "***strongest Abstral quarter to date***" as the fourth quarter of 2014—the quarter that started with the signing of the rebate agreement. *See infra* ¶96. And Galena continued to report revenue numbers that were ***consistently materially higher*** than Galena's revenue numbers in 2013 and early 2014 (when Drs. Ruan and Couch had been prescribing massive amounts of Abstral but when most those

[13] The chart was presented as evidence in their criminal trial of Drs. Ruan and Couch. The writing on the chart was made by counsel for the U.S. Attorneys' Office.

prescriptions were provided at the expense of Galena under the voucher program), with Galena announcing for the first quarter 2015 its "***second-highest quarter of net revenues since our relaunch of Abstral in 2013***" (¶99), and announcing for the second quarter of 2015 Galena's new ***"strongest net revenue quarter to date***" (¶101). Specifically, as set forth *infra*, ***after*** entering into the rebate agreement with Drs. Ruan and Couch, Galena reported revenue of: (1) "$3.2 million in the fourth quarter of 2014 and $9.3 million for the year ended December 31, 2014, compared to $1.3 million and $2.5 million, respectively, for the same periods of 2013" (¶96); (2) "$2.8 million in the first quarter of 2015, ***a 28% increase*** compared to $2.2 million for the same period a year ago" (¶99); and (3) "$3.4 million in the second quarter of 2015, ***a 48% increase*** compared to $2.3 million reported for the same period in 2014[.]" ¶102. It is, indeed, reasonably inferable that the prescriptions by Drs. Ruan and Couch in 2015 were predominantly responsible for these revenue numbers given that following the government raid and shutdown of Drs. Ruan and Couch's PPSA clinic in May 2015, Galena was unable to even continue manufacturing and selling Abstral.

77. By providing percentage payments to C&R Pharmacy (owned by Drs. Couch and Ruan) for the prescriptions of Abstral filled there, Galena was paying Drs. Ruan and Couch for the prescriptions of Abstral they wrote—the definition of a kickback. Accordingly, the DOJ would later allege in a lawsuit filed in the District of New Jersey that the rebate agreement was an illegal kickback given in exchange for writing prescriptions for Abstral. *See supra*. Further, because Defendants entered into the rebate agreement with Drs. Ruan and Couch's pharmacy ***after*** Defendants Lento and Schwarz had been specifically told by Dr. Ruan that PPSA treated few, if any, cancer patients, the rebate agreement was not only an illegal kickback, it also constituted ***off-label promotion*** of a drug for an unindicated purpose.

c. Additional Off-Label Promotions by Lento and Schwartz

78. Despite the fact that PPSA was consistently (if not exclusively) prescribing Abstral to non-cancer patients (regardless of legitimate medical need), and despite the fact that Defendants

Lento and Schwartz knew since October 2013 that, according to Dr. Ruan, PPSA did not treat cancer patients with breakthrough cancer pain (such as to qualify for what Dr. Ruan misunderstood were the requirements for participation in Galena's RELIEF program), Defendants continually promoted and encouraged Dr. Ruan and Dr. Couch to prescribe Abstral for off-label purposes throughout the Class Period.

79. To be sure, evidence presented at the criminal trial of Drs. Ruan and Couch demonstrate that ***Defendants Schwartz and Lento***, along with other Galena representatives, frequently communicated with Drs. Ruan and Couch and even traveled to Mobile for promotional visits with the two doctors.

80. For example, according to an email between ***Defendant Lento*** and Dr. Ruan by December 5, 2013, the two had "discussed in [] previous conversations" the opportunity for Dr. Ruan to be "involved with Galena at the highest advisory/consultatory level."[14] Other evidence showed that ***Defendant Lento***, along with David Corin (National Director of Sales) and Jeff Palmer (Galena's sales representative), took a trip to Mobile on February 25, 2014 to visit with Drs. Ruan and Couch who were upset with the Company because the stock price had dropped significantly after certain Galena insiders made massive stock sales—actions that became the subject of a Cease and Desist Order by the SEC.[15] David Corin explained that he knew Drs. Ruan and Couch were upset about the

[14] Dr. Couch attended at least one of Galena's Advisory Board Meetings, for which, according to the US Department of Justice, Galena paid Dr. Couch $5,000 plus expenses. According to other emails presented during the trial, Dr. Ruan ultimately decided not to attend Galena's Advisory Board Meeting due to concerns that he might hear inside information that would prevent him from trading his Galena stock, since he and Dr. Couch "plan[ned] to sell quick on the side." Dr. Ruan explained this reasoning in a January 18, 2014 email to Dr. Couch, adding "[m]aybe I'm just paranoid, but since [sic] we both have purchased some stocks and we use their products more than others."

[15] Galena's former CEO Mark Ahn, CFO Ryan Dunlap, and Senior VP of Investor Relations Remy Bernarda were themselves defendants in an earlier securities fraud action, *In re Galena Biopharma, Inc. Sec. Litig.*, No. 3:14-cv-367-SI (D. Or.), which alleged that Galena and certain of its officers and directors committed a classic "pump and dump" manipulation scheme, whereby they paid third-party

insider sales because "[t]hey sent several emails to my boss, whose name was ***Chris Lento***, and others in the organization. And I was—I had been forwarded those messages."

81. Other testimony and evidence showed that, at the behest of ***Defendant Schwartz***, Corin made several other trips to Mobile immediately prior to and during the Class Period to visit Drs. Ruan and Couch, including trips on September 24, 2014, January 20, 2015, and April 21, 2015. According to Corin, "[Schwartz] wanted us [Galena representatives] to be more consistent in how often we came" to visit Drs. Ruan and Couch. Corin explained that "[Schwartz] wanted us to have a more regular cadence in our visits" to Drs. Ruan and Couch "[b]ecause other companies were visiting consistently and the higher-ups in those companies, as well – from CEOs to most C-level employees. It was important that we had a presence as well." Corin confirmed that other companies, including Insys, sent their CEOs and other high-level people to meet with Dr. Ruan and Dr. Couch, and that this was part of "what prompted more meetings or the need for more regular meetings [with Drs. Ruan and Couch] from executives at Galena." Corin explained that Dr. Ruan "made clear that we weren't giving them the same attention that other customer – other companies were." Corin elaborated that "[h]e [Dr. Ruan] explained it very clearly that we weren't doing enough. As a business, we weren't listening to them [Dr. Ruan and Dr. Couch] enough and we weren't going to be successful."

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newsletter writers to post articles touting Galena stock. The articles, which purported to be authored by credible investment professionals, never disclosed that they were paid promotions, and Galena never disclosed the Company was using such stock promoters that on their face appeared to be independent. As a result of the third-party promotions, Galena's stock price nearly quadrupled, and Galena insiders quickly sold almost all their stock, reaping approximately $16 million in personal profits. The parties reached a settlement of these claims. On April 10, 2017, the SEC announced it had reached a settlement with Galena for charges the SEC had brought stemming from this stock manipulation scheme. As part of the SEC settlement, Galena and its former CEO, Defendant Ahn, agreed to cease and desist from future securities laws violations, and Ahn was prohibited from acting as an officer or director of any registered issuer of securities. Defendant Ahn agreed to disgorge $677,250, pay prejudgment interest of $67,181, and a civil penalty of $600,000. Galena agreed to pay a civil penalty of $200,000.

82. ***Defendant Schwartz***, Galena's CEO, also made at least two trips to Mobile during the Class Period to visit with Drs. Ruan and Couch during the Class Period: one trip in November 2014 and one trip in February 2015. David Corin explained that Defendant Schwartz made these trips to Mobile "[b]ecause Dr. Ruan and Dr. Couch wanted to meet with him [Schwartz]." According to Corin, "[i]t was demanded by Dr. Ruan that he [Schwartz] meet with him [Ruan]."

83. Defendants knew that Drs. Ruan and Couch treated almost exclusively non-cancer patients to the point that Dr. Ruan mistakenly thought his patients would be ineligible to participate in Galena's RELIEF registry program. Defendants, however, repeatedly and continually promoted Abstral to Drs. Ruan and Couch, and Defendants encouraged and offered incentives to these doctors, so they would continue prescribing Abstral for off-label purposes. Defendants also actively sought to help Drs. Ruan and Couch get prior authorizations for their Abstral prescriptions to non-cancer patients, including David Corin's January 20, 2015 trip to Mobile to "introduce Dr. Ruan and Dr. Couch to Steven Brennan" who "was responsible for [Galena's] GPS program, which was our prior authorization program." Such promotions and incentives were undoubtedly due to the fact that Drs. Ruan and Couch prescribed such large amounts of Abstral. As Corin testified, Drs. Ruan and Couch were "important individuals for Galena":

> Q: Were Dr. Ruan and Dr. Couch important clients or important individuals for Galena Biopharma?
>
> A: Yes.
>
> ***
>
> Q: ***Why were Dr. Ruan and Dr. Couch important to Galena Biopharma?***
>
> A: ***Because they were our highest Abstral prescribers.***
>
> Q: ***And was it highest by a large margin?***
>
> A: **Yes**.

84. Defendants' frequent trips and meetings with Drs. Ruan and Couch (as well as the kickbacks paid by Galena to Drs. Ruan and Couch pursuant to the rebate agreement and the RELIEF Program for which Dr. Couch participated, discussed *supra*) constituted illegal promotions of Abstral for off-label purposes.

3. Defendants Knew Drs. Ruan, Couch, and Rho Were Overprescribing Abstral for Non-Medically Necessary Purposes

85. Throughout the Class Period, Defendants were aware that Drs. Ruan and Couch were the two largest Abstral prescribers by huge and inordinate margins. Indeed, just these two doctors accounted for approximately 30% of all Abstral sales in the county. *See* Exhibit 1, attached hereto.

86. According to Corin's testimony, Galena kept "an internal document that [Galena] would send out on a quarterly basis with all of our prescribers in the country, how many prescriptions they had written each quarter." The internal Galena document showed that from third quarter 2013 through fourth quarter 2014, ***Dr. Ruan wrote 1,302 prescriptions*** for Abstral, and ***Dr. Couch wrote 649 prescriptions*** for Abstral. As David Corin (Galena's National Sales Director) testified, the only doctor "in the ballpark with" Drs. Ruan and Couch was Dr. Rho—another "pain management doctor" who was a known shareholder of Galena and who also predominately treated, and prescribed Abstral to, non-cancer patients—who ***wrote 611 prescriptions*** for Abstral. *See* Exhibit 1. By comparison, ***the next highest prescriber*** of Abstral (*i.e.*, the fourth highest Abstral prescriber in the country) during that same period ***wrote only 153 prescriptions*** for Abstral. *Id.* In other words, Dr. Ruan wrote ***851%*** more Abstral prescriptions than the fourth highest prescriber of Abstral in the country, and Dr. Couch wrote ***424%*** more Abstral prescriptions than the fourth highest prescriber in the country.

87. Indeed, as demonstrated in Exhibits 1 and 5 (attached hereto), Dr. Ruan and Dr. Couch went from writing essentially no prescriptions of Abstral to writing copious amounts of Abstral over the course of just a few months. *Id.* The amount of Abstral prescriptions suddenly being written by

Drs. Ruan and Couch were notably inordinate not only to their prior lack of such prescriptions but also compared to the number of prescriptions written by other doctors. *See* Exhibit 1. Both of these facts were readily observable to Defendants, as they kept track of each doctors' prescriptions of Abstral, as evidenced by Exhibit 1 (the internal Galena document) and as further evidenced by the document provided by CW, which listed doctors' Abstral prescriptions in dollar amount by month. *See also, infra*, ¶93, (Lento describing Galena's "internal metrics" that Defendants were "monitoring" and "keeping track of," including daily sales, average prescription price, number of prescribers" for Abstral).

88. It is almost impossible to imagine that Defendants did not realize that these doctors were overprescribing Abstral for non-legitimate purposes. Such an astronomical number of sudden Abstral prescriptions by these two doctors—who had already told Defendants point blank that they treated very few, if any, appropriately indicated patients—simply could not be explained as anything *other* than the overprescribing of a highly addictive and dangerous drug for non-medically necessary purposes.

89. To be sure, Drs. Ruan and Couch were convicted of prescribing Abstral for non-medically necessary purposes outside the usual course of professional practice. As, Justin Palmer (a nurse practioner at PPS) testified that PPSA "didn't have many cancer patients," and for the entire period "from 2011 to 2015," he had seen maybe "10 or 15 active cancer patients." Bridgette Parker, another nurse practitioner at PPSA from 2012 until its shutdown in May 2015, further testified that she thought the off-label uses for which Dr. Ruan and Dr. Couch prescribed Abstral were inappropriate, saying "I felt that it was used often when it shouldn't be." Ms. Parker also confirmed that both Dr. Ruan and Dr. Couch "asked" or "encouraged" her to prescribe Abstral to patients even when there did not appear to be a need for it or when the patients said their current prescriptions "were working okay."

90. Defendants knew, or should have known in the absence of extreme recklessness, that Drs. Ruan and Couch were illegally prescribing Abstral for improper non-medically necessary purposes. The sheer number of prescriptions being written by these two doctors when compared to other doctors (and their own prior lack of prescriptions) was a significant red flag that could not have gone unnoticed by Defendants.

4. Defendants Knew That Abstral Sales Were Artificially Inflated and Thus Unsustainable

91. Eventually, the illegal practices of Drs. Ruan and Couch in overprescribing and dispensing Abstral were brought to an end. The shutdown of Drs. Ruan and Couch's "pill mill" also marked the end of Galena's Abstral division. As David Corin testified:

Q: Do you know what, if anything, occurred in ***late May of 2015*** regarding Dr. Ruan and Dr. Couch?

A: ***Our understanding is that their practice was shut down.***

Q: Following the shutdown of their practice, what happened to prescriptions for Abstral?

A: In regards to Dr. Ruan and Dr. Couch?

Q: In regard to overall number of prescriptions written for Abstral after Dr. Ruan and Dr. Couch's practice was shut down?

A: ***Our volume dropped.***

Q: Did it drop by a little bit or did it drop significantly?

A: ***Significantly***.

Q: What then happened to Galena's ability to promote Abstral?

A: We were limited because ***we couldn't make up that revenue***. And eventually Galena was forced to sell the product in December of 2015.

***

Q: At what point did you leave Galena?

A: December 31st, 2015.

Q: Did you leave on your own or were you fired?

A: The commercial team was dissolved.

Q: Why was the commercial team dissolved?

A: There were no commercial products to sell.

Q: And is that after Abstral was sold off?

A: Abstral and Zuplenz, which was our other product.

92. Defendants knew, or should have known in the absence of extreme recklessness, that Abstral sales were largely supported by two pain management doctors prescribing inordinately large amounts of Abstral to non-cancer patients, and that these sales were unsustainable given the government's aggressive oversight of prescription opioids.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS VIOLATED SECTIONS 10(B) AND 20(A) OF THE EXCHANGE ACT AND SEC RULE 10B-5

A. Defendants' Materially False or Misleading Statements

1. November 3, 2014 and November 5, 2014 Statements

93. The Class Period begins on November 3, 2014. On November 3, 2014 and November 5, 2014, Defendants reported Galena's third quarter 2014 results and, in doing so, issued several materially false or misleading statements:

a) Galena's press release, dated November 3, 2014, reported "***[n]et revenue for the third quarter of 2014 was $1.6 million compared to $1.2 million for the third quarter of 2013, an increase of 25%. Net revenue for the nine months ended September 30, 2014 was $6.1 million***. The third quarter of 2013 was the first quarter that the company generated net revenue." Galena's press release also quoted Defendant Schwartz as stating: "'The company continues to make excellent progress on our clinical programs, and we continue to build our commercial franchise.'" (Press Release issued November 3, 2014; *see also* Form 10-Q filed November 5, 2014, signed by Schwartz).

b) [Lento:] "I will begin to [sic] Abstral, our lead commercial asset. Abstral is a transmucosal immediate release fentanyl, or TIRF product, ***indicated for the treatment of breakthrough pain in opioid tolerant <u>cancer</u> patients***. As noted in our press release, and as Ryan will review in greater detail, our Abstral net revenue was $1.6 million in Q3. As discussed last quarter, this increase in revenue was expected, and was a result of fluctuations in inventory at the wholesale and distribution level. This is not uncommon, as we're still in the first year of our product launch.

Our daily paid prescriptions or pulled through sales from our customers have continued to improve through the end of Q3, with an even stronger demand in the first month of Q4. Over time, we expect the ex-manufacturer sales to more closely reflect our daily paid prescription volume. As a reminder, Abstral is a supportive care therapy in a segmented and highly competitive market.

According to Wolters Kluwer, ***our market share of the branded TIRF market in September remained steady with 6% of total prescriptions***. The size of the overall TIRF market has fluctuated since our launch, and we remain focused on targeting ***the long-term and sustainable business within the market.*** We strongly believe in the potential of Abstral because of its unique clinical attributes, which are advantageous for patients.

We have spent the first year of ***our launch*** developing strong relationships with the ***appropriate healthcare providers who are treating the appropriately indicated patients***. The foundation of our Abstral strategy was built upon ensuring product access and insurance coverage for all ***identified patients***.

***

For Abstral, we remain on track to achieve our guidance projections in 2014. ***While we're on [sic] only one month into the quarter, many of our internal performance metrics, including whole-seller and distributor sales reports, as well as REMS and IMS data, report towards -- point towards our strongest quarterly performance to date***." (Earnings conference call on November 3, 2014, with Schwartz and Lento participating).

c) [Schwartz:] "Thank you, Ryan. As we look back on our first year of commercial activities, we're proud of the structure we have built. While Chris highlighted some the challenges, we also know how to address and adapt to them, as the market has changed for Abstral***, our commercial team has refined our strategy to ensure the long-term viability and profitability of the franchise***.

We'll be taking the same expertise into our launch of Abstral. ***As a result, we plan to increase our Abstral revenues by over 50% next year and are setting our 2015 net revenue guidance to between $15 million and $18 million***." (Earnings conference call on November 3, 2014, with Schwartz and Lento participating).

d) [Analyst] "… Could you talk a bit more about what you're seeing, what are the signs that the distributors and wholesalers are starting to hone in on the right level of inventory for Abstral to better match the demand, quarter over quarter? And what sort of inventory build are you expecting in 4Q?

[Lento:] "I'll take the first part of that question. ***Some of the internal metrics we are monitoring, as you know, we're keeping track of daily sales, average prescription price, number of prescribers, and we're off to a terrific start in Q4***. Along with our wholesale and distributor partners, we're learning how to manage Abstral during this year. It is a product six strengths being managed – being

managed at eight different wholesalers, with dozens of distribution centers. So we are feeling more confident in our ability, and in our partners' ability to manage the inventory moving forward." (Earnings conference call on November 3, 2014, with Schwartz and Lento participating).

e) "In March of 2014 we launched the Galena Patient Services (GPS) program, a full service support program designed to navigate patient access to Abstral that is coordinated through a third party vendor. Along with the launch of GPS, we also made changes to our patient assistance program (PAP) to reduce the use of free product vouchers and rely more heavily upon an expedited prior authorization process. These changes resulted in both a flattening in the growth in prescription demand and significant improvement in gross-to-net deductions, quarter-over-quarter in 2014. ***We believe the slowed growth in quarter-over-quarter prescription demand is the temporary result of our GPS program and PAP rules changes, and we anticipate an increase in prescription demand and ex-manufacturer sales in the last quarter of 2014***." (Form 10-Q filed November 5, 2014, signed by Schwartz).

[Emphasis added.]

94. Defendants' November 3, 2014 and November 5, 2014 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading. Among other things, by touting Abstral's revenues and expected revenues (bullet a-e) and favorable "market share" (bullet b) while attributing Abstral's sales to "appropriate healthcare providers who are treating the *appropriately indicated patients*" (bullet b), Defendants misled investors into thinking that the Company's Abstral sales were sustainable through legitimate sales practices and promotions to physicians prescribing for on-label indications and/or actual medical need; in reality, however, Abstral's revenues were reliant on Galena's illegal off-label promotions and illegal kickbacks. In particular, Defendants' statements touting "stronger demand in the first month of Q4" (bullet b), that "internal performance metrics" for the first "month into the quarter" "point towards our strongest quarterly performance to date" (bullet b), and that "we're off to a terrific start in Q4" (bullet d) while only attributing sales as deriving from legitimate practices such as "ensuring product access and insurance coverage for all *indicated* patients" (bullet b) were materially misleading; in truth, Defendants' knew that the increase in Abstral sales in the first month of Q4 was *largely based on the*

rebate agreement that Defendant Schwartz had entered into with C&R Pharmacy on October 1, 2014, which provided significant kickbacks to Drs. Couch and Ruan for the Abstral prescriptions they wrote. *See* Exhibit 5 (showing extreme increase in the doctors' Abstral prescriptions in October 2014). Similarly, Defendants statements that "we plan to increase our Abstral revenues by over 50% next year and are setting our 2015 net revenue guidance to between $15 million and $18 million" (bullet c) and that "we anticipate an increase in prescription demand and ex-manufacturer sales in the last quarter of 2014," while attributing the expectation of increased sales in Q4 and 2015 to innocent causes such as the "commercial team's refined strategy" (bullet c) and the dissipation of the temporary slowdown "following Galena's GPS program and PAP rules changes" (bullet e) were materially false or misleading; here again, such expectations were largely based on the illegal kickback arrangement with C&R Pharmacy.

95. Indeed, Defendants' statements were materially misleading because they failed to disclose that: (1) the touted financial results and guidances were achievable only through Galena's illegal promotion of Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral (including kickbacks for prescriptions that were known to be off-label); and (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two disreputable pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks. These omissions were material since these undisclosed facts created a significant risk that Abstral revenues were unsustainable and that the Company would be subjected to litigation and/or liability for its illegal conduct.[16]

[16] Indeed, Galena's Form 10-Q evidence Defendants' knowledge that their illegal conduct subjected them to an increased likelihood of liability, with Galena stating: "[A] drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling…. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution."

2. March 5, 2015 Statements

96. On March 5, 2015, the Company announced its fourth quarter and year end 2014 financial results and, in doing so, issued several materially false or misleading statements:

a) "***Net revenue was $3.2 million in the fourth quarter of 2014 and $9.3 million for the year ended December 31, 2014, compared to $1.3 million and $2.5 million, respectively, for the same periods of 2013***…. Dr. Schwartz continued,…[,] ['a]dditionally, ***we anticipate the commercial arm of our business to continue to grow revenue, while enhancing our relationships in the oncology community*** as our development pipeline advances. ***As reported today, we recorded our strongest Abstral quarter to date, hitting above the middle of our guidance range for the year***, and with the addition of our second commercial product in Zuplenz, we expect to nearly double our overall commercial sales in 2015.'… Dr. Schwartz concluded, 'Our commercial and clinical teams have done a tremendous job over the past year to advance our multiple programs. ***As I assess our company, I am not only excited about the next 6-12 months, but for the long-term prospects of Galena Biopharma***.'"(Galena's March 5, 2015 press release; *see also* Form 10-K filed March 5, 2015, signed by Schwartz).

b) [Schwartz:] "Our focus is on building Galena into a leading oncology Company. We established our commercial franchise as a strategic component for ***long-term growth, and sets a foundation for our future***. . . . As Chris will elaborate, the relationships that our commercial team is making now with key ***oncology*** healthcare providers, distributors, and managed care groups are not only extremely valuable for selling our current products, but also provide the ability to quickly add future products**.** Finally, ***we expect the commercial business to maximize revenues, become accretive, and provide money to the Company*** to help fund our development assets and minimize shareholder dilution." (Earnings conference call with Defendants Schwartz and Lento participating).

c) [Lento:] "Thank you, Gavin. Today I will walk you through the 2014 successes we have had with our flagship product Abstral….

As noted in our press release, and as Ryan will review in greater detail, ***our actual net revenue was $9.3 million in 2014. We achieved this number with a focused sales effort, and we are excited for continued growth of Abstral in 2015.*** As a reminder, ***Abstral is indicated for the treatment of breakthrough cancer pain***, and it is a TIRF, or a transmucosal immediate release fentanyl, product. As Mark mentioned, ***Galena is an oncology Company***, and we are steadfastly focused on building Galena's commercial business within the oncology space.

…With that background, I would like to walk you through the metrics are use to evaluate our business. We acquired the US marketing rights for Abstral from Orexo and relaunched the product in the fourth quarter of 2013. ***We relaunched Abstral that had previously sold approximately $1 million over its previous 12-month period, and we were able to grow the brand to $9.3 million in net revenue***

> ***in 2014. We believe that we can continue to grow Abstral***, and our successful commercialization will carry over to the relaunch of Zuplenz in Q2.
>
> ***
>
> ***In addition, on slide number 21 you can see the dramatic impact of our patient assistance rule changes and our GPS services have had on increasing the average number of Abstral units dispensed per pay transaction.*** In December 2013, the average units of Abstral per ***pay*** transaction was roughly 42 tablets. ***Fast forward to December 2014, and the average number increased roughly 60% to 69 tablets per transaction. In addition to GPS and the program rule changes, providers have become more comfortable prescribing Abstral for their breakthrough cancer pain patients***." (Earnings conference call with Defendants Schwartz and Lento participating).

[Emphasis added.]

97. Defendants' March 5, 2015 statements (in Galena's press release, Form 10-K, and earnings call) were materially false or misleading. Specifically, Defendants' statements touting the Company's revenues and prospects for future revenues (bullets a-c) and the "strongest Abstral quarter to date" (bullet a) while attributing those record revenues to the legitimate practices such as the successful GPS program and increased Abstral prescriptions to "breakthrough cancer pain patients" (bullet c), were materially false or misleading because the increased revenues were actually the result of illegal and unsustainable practices. In particular, the record Abstral revenues (bullet a) and the significant increase in paid transactions in December 2014 compared to December 2013 (bullet c) were largely the result of the illegal rebate agreement that Defendant Schwartz signed with C&R Pharmacy, which provided significant kickbacks to Drs. Couch and Ruan for the non-voucher Abstral prescriptions they wrote. Indeed, by the time of these statements, Galena had paid more than $97,000 in "rebates" to Drs. Ruan and Couch for their knowingly off-label Abstral prescriptions written to non-cancer patients. *See also* Section IIV.C.2.b, *supra* (showing that more than $1.257 million of Galena's first quarter revenue came from Drs. Ruan and Couch's prescriptions).

98. Thus, Defendants' statements were materially misleading because they failed to disclose that: (1) the touted financial results were achieved through Galena's illegal promotion of

Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral (including kickbacks for prescriptions that were known to be off-label); and (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two disreputable pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks. These omissions were material since these undisclosed facts created a significant risk that Abstral revenues were unsustainable and that the Company would be subjected to litigation and/or liability for its illegal conduct.

3. May 7, 2015 Statements

99. On May 7, 2015, the Company announced its financial results for the first quarter ended March 31, 2015 and, in doing so, issued several materially false or misleading statements:

a) "***Net revenue was $2.8 million in the first quarter of 2015, a 28% increase compared to $2.2 million for the same period a year ago***…. Dr. Schwartz concluded, '***[O]n the commercial front, Abstral sales remain on target, our oncology presence continues to grow, and we reiterate our full year guidance of $15-$18 million for 2015***. Additionally, we are now preparing to launch Zuplenz in July, adding a second, supportive care commercial product to our oncology-focused sales portfolio. In total, ***we have established a strong foundation with our development programs supported by our commercial franchise***, and we remain committed to the growth of our company.'" (Galena's May 7, 2015 press release; *see also* Form 10-Q filed May 7, 2015, signed by Schwartz).

b) [Schwartz:] "***In addition to the development team's accomplishments, our commercial team recorded its second-best quarter of net revenue in the best back-to-back month since Abstral's product launch. Most importantly, we continued our increased penetration within the oncology space*** as we head into the launch of our second commercial oncology supportive care product, Zuplenz." (Earnings conference call, with Defendants Schwartz and Lento participating).

c) [Lento:] "Thank you, Gavin, and good afternoon, everyone. ***As we shared with today's earnings release and as shown on slide number 11, we reported actual net revenue of $2.8 million for the first quarter of 2015, our second-highest quarter of net revenues since our relaunch of Abstral in 2013. In addition, the overall trend line as measured by end-user product demand continues to grow with March representing one of our best months to date.*** Equally important, our gross to net deduction also improved this quarter, from 63% in Q4 2014 to 65% in Q1 2015. ***One month into the second quarter, our performance metrics indicate a very strong month for Abstral in April as measured by customer***

> ***demand***, but please remember that this is not a direct correlation to our net revenue, which is recorded based on ex-factory sales.
>
> ***We continue to focus on refining Abstral's prescription fulfillment process as depicted on slide number 12. As a reminder, Abstral is an indicator for the treatment of breakthrough cancer pain in opioid tolerant adult cancer patients.***
>
> ***
>
> Our current market share in the branded turf market remains steady at around 5% of total prescriptions on a monthly basis measured by Wolters Kluwer. ***While our salesforce continues to call on pain specialists who are treating a large number of cancer patients, our long-term strategy is to develop lasting relationships with medical oncologists, radiation oncologists, and palliative care specialists since we believe this represents the most stable market, the best potential for Abstral, and meets the goals as an oncology-focused organization.***" (Earnings conference call, with Defendants Schwartz and Lento participating).

[Emphasis added.]

100. Defendants' May 7, 2015 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading. Defendants' statements touting Abstral's revenues (bullets a, c, and d) and attributing that revenue to legitimate on-label prescriptions for "oncology" (bullets a and b) and Abstral's legitimate sales practices to "medical oncologists, radiation oncologists, and palliative care specialists" and "pain specialists who are *treating a large number of cancer patients*" (bullet c), were materially false or misleading because the increased revenues were, in reality, the result of illegal and unsustainable practices that encouraged the over-prescriptions of Abstral for non-medically necessary purposes. In particular, the record Abstral revenues were largely the result of the rebate agreement that Defendant Schwartz signed with C&R Pharmacy, which provided significant kickbacks to Drs. Couch and Ruan for the Abstral prescriptions. Indeed, while Defendants touted that "March represent[ed] one of our best months to date" due to "end-user product demand continu[ing] to grow" (bullet c), it is evident from the chart of Drs. Ruan and Couch's prescriptions that Abstral sales in March were largely fueled by the increased prescriptions written by Drs. Ruan and Couch following the execution of the rebate agreement. *See* Exhibit 5, attached hereto.

101. Thus, Defendants' statements were materially misleading because they failed to disclose that: (1) the touted financial results were achieved through Galena's illegal promotion of Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral (including kickbacks for prescriptions that were known to be off-label); and (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two disreputable pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks. These omissions were material since these undisclosed facts created a significant risk that Abstral revenues were unsustainable and that the Company would be subjected to litigation and/or liability for its illegal conduct.

4. August 6, 2015 Statements

102. On August 6, 2015, Galena announced its financial results for the second quarter ended June 30, 2015 and, in doing so, issued a series of materially false or misleading statements:

a) Galena's press release, dated August 6, 2015, reported "***[n]et revenue was $3.4 million in the second quarter of 2015, a 48% increase compared to $2.3 million reported for the same period in 2014. Net revenue was $6.1 million in the first half of 2015, a 36% increase compared to $4.5 million reported for the same period in 2014***." Galena's press release also quoted Defendant Schwartz as stating: "'***And, today we reported improved Abstral sales quarter over quarter resulting in our strongest net revenue quarter to date. Based on current projections, we anticipate that we will come in closer to the lower end of our guidance range, at around $15 million for the year***.'" (Press Release issued August 6, 2015; *see also* Form 10-Q filed August 6, 2015, signed by Schwartz).

b) [Schwartz:] "***As we noted in our press release, we recorded net revenue of $6.1 million thus far this year from Abstral sales, and are very proud of our Commercial team for bringing in our highest quarterly net revenue to date of $3.4 million in Q2.***

Abstral is part of the transmucosal immediate release fentanyl, or TIRF, market that is very competitive, and has received a great deal of press this year. ***As Chris will go into in more detail, our metrics for Abstral are trending in the right direction, although our sales growth has fluctuated quarter-over-quarter based on field demand and wholesaler inventory levels.***

Because of the ongoing market dynamics, the quarterly variability around our reported sales, and the fact that we've just launched Zuplenz and have yet to

recognize revenue to date for that product, it is appropriate for us to guide to a lower end of our range with the expected full-year revenue of around $15 million for both products. We continue to work to make our Commercial business accretive, and we are evaluating our commercial options and strategy to achieve long-term profitability and maximize the value of our commercial assets, with a goal of building shareholder value." (Earnings conference call on August 6, 2015 with Defendants Schwartz and Lento).

c) [Lento:] "Thank you, Gavin. And good afternoon, everyone. I'll start my discussion with Abstral. As a reminder, Abstral is indicated for the treatment of breakthrough cancer pain in opioid-tolerant adult cancer patients, and falls under the TIRF REMS Access program. ***I am pleased to report Abstral net revenue of $3.4 million for the second quarter of 2015 -- our highest net revenue quarter since launch.***

This is a result of our team adding new prescribers and the continued adoption of our Galena patient services, or GPS program. On slide 16, you can see this trajectory. In addition, our gross to net deduction improved to 77% this quarter compared to 65% in Q1 2015.

***

As we have mentioned on previous calls, the growth of Abstral will continue to fluctuate quarter-over-quarter. But as you have seen, the underlying metrics are all trending upwards.

***

Our account management team has secured product availability with all of our distribution partners, assuring product access for all healthcare providers ***and their appropriate patients.***

***

In summary, ***our Abstral business is growing***, and we are enthusiastic about selling Zuplenz where our very early reception of the product has been positive." (Earnings conference call on August 6, 2015 with Defendants Schwartz and Lento participating).

[Emphasis added.]

103. Defendants' August 6, 2015 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading because they falsely asserted that Abstral's "underlying metrics are all trending upwards" (bullet c) or in the "right direction" (bullet b) and that "our Abstral business is growing" (bullet c), when the exact opposite was true. In truth, the two

doctors responsible for ***30%*** of the Company's Abstral prescriptions had been arrested and their ***businesses shut down in May 2015***, which resulted in "significantly" reduced Abstral sales (as David Corin, Galena's National Sales Director, testified). Moreover, while Defendants attributed the disappointing earnings to "ongoing market dynamics" (bullet b), this was materially misleading given that the actual reason for the lower earnings was that Galena had lost its two top Abstral prescribers because the doctors had been arrested for writing illegal prescriptions outside the usual course of professional practice and not for a legitimate medical purpose—illegal prescriptions that had been induced by Defendants. Thus, Defendants' statements misled investors by failing to disclose that Abstral's revenues were not sustainable, certainly not at the reported level. Defendants' statements were also materially misleading because they attributed the disappointing earnings entirely to normal circumstances when, in truth, Defendants' had facilitated the illegal prescriptions that prompted the raid of PPSA through illegal kickbacks and off-label promotions to Drs. Ruan and Couch who were overprescribing Abstral for non-medically necessary purposes.

104. On the news of Galena's disappointing earnings and reduced revenue guidance, the Company's stock price fell $0.12, or 7.4%, from its closing price of $1.63 on August 6, 2015 to close at $1.51 on August 7, 2015. The August 6, 2015 disclosures of lower earnings and expectations partially revealed the risks concealed by Defendants' misstatements. In particular, these disclosures revealed the materialized risk that Abstral sales would drop off when the illegal promotion by Galena and illegal prescriptions for Abstral written by Galena's top two prescribers could not be sustained. Indeed, this is exactly what happened when (although not disclosed by Galena) law enforcement closed down Drs. Ruan and Couch's practices, clinics, and pharmacy in late May 2015. This disclosure, however, was only partially corrective. Galena's stock price would have dropped more if the full truth had been revealed. Indeed, the August 6, 2015 disclosures were both actionably misleading and partially corrective.

B. The Truth Emerges

1. November 9, 2015 Partial Corrective Disclosure

105. On November 9, 2015, Galena announced in a press release that it had decided to divest its commercial business, which included Abstral. As such, the Company's commercial business activities were classified as "discontinued operations," and Galena stated that it anticipated exiting the commercial business by the end of the first quarter of 2016. In making this announcement, Galena made the following materially false or misleading statements, quoting Schwartz:

> "Dr. Schwartz continued, '***When I assumed the position of President and CEO of Galena, I, along with our executive team, began a careful examination of our operations and assets to determine the optimal strategy for Galena that would enable the greatest opportunity for growth, while maximizing shareholder value. As a result of this analysis and review by our Board of Directors, we have concluded that it is in the best interest of our patients, our shareholders, and the long-term success of our company to focus our energy and resources exclusively on our clinical development programs.*** Since acquiring the products we have significantly grown the sales of Abstral and successfully launched Zuplenz, and I believe that each has strong commercial potential and offers significant benefits to their respective patient populations. ***However, the foundation of Galena has always been our cancer immunotherapy programs, which are now rapidly advancing towards several key inflection points. Therefore, we believe it is important for Galena to focus on our core expertise and the successful advancement of our late and mid stage clinical pipeline.*** We appreciate the dedication and hard work of the commercial team as we transition out of the commercial business and are extremely grateful for all of their efforts.'
>
> Dr. Schwartz concluded, 'For both patients and shareholders of Galena, there is a much greater opportunity to generate value if we dedicate all of our resources to our clinical programs, and we are eager to move the company in this new direction….'"
>
> [Emphasis added.]

106. On the November 9, 2015 news, the price of Galena common stock fell $0.19 per share, or 11%, to close at $1.53 per share on November 10, 2015. The November 9, 2015 disclosures of the discontinuation of Galena's commercial business further partially revealed even more of the risks concealed by Defendants' misstatements. That is, these disclosures revealed the risk concealed by Defendants that the commercial operations of Galena could not be sustained without the illegal promotion by Galena and illegal prescriptions for Abstral written by Galena's top two prescribers.

These disclosures revealed the severity of those risks in that the sales drop off (more than 30% of the Abstral business lost when Drs. Ruan and Couch were forced to shut down) was so pronounced that Galena's entire commercial business had to be discontinued. But the disclosure of these materialized risks was only partially corrective as to Defendants' materially false and misleading statements because they did not disclose the underlying causes of the risks that materialized and thus concealed Galena's potential civil and criminal exposure. The price of the stock would have dropped even more if the full truth had been revealed.

107. On November 20, 2015, the Company announced that it had sold its Abstral product to a private company in a deal valued at up to $12 million, with $8 million cash up-front, and up to $4 million in additional cash upon the achievement of certain sales milestones, effective as of November 19, 2015.

2. December 22, 2015 Partial Corrective Disclosure

108. On December 22, 2015, the Company announced in a press release the receipt of a federal subpoena in connection with its sales of Abstral. In the press release, Defendants disclosed:

> On December 16, 2015, Galena Biopharma, Inc. ("Galena") received a subpoena from the U.S. Attorney's Office for the District of New Jersey. The subpoena requests the production of a broad range of documents pertaining to marketing and promotional practices related to the product ABSTRAL® (fentanyl) Sublingual Tablets. Galena intends to cooperate with the government's investigation. Galena can make no assurances as to the time or resources that will need to be devoted to this inquiry or its final outcome, or the impact, if any, of this inquiry or any proceedings on Galena's business, financial condition, results of operations and cash flows.

109. On this news, the price of Galena common stock fell $0.06 per share, or 3.6%, to close at $1.57 per share on December 23, 2015. This disclosure for the first time revealed Galena's potential exposure to liability for its promotion of Abstral. But, the December 22, 2015 disclosures were only partially corrective. Among other things, the press release did not reveal that Abstral's top two prescribers' practices had been shut down and were then-being investigated by the government for their excessive fentanyl prescriptions, nor that Galena employees, including its CEO,

had been providing significant kickbacks to these doctors, thereby incentivizing them to overprescribe Abstral for non-medically necessary purposes. Thus, the extent of Galena's exposure to liability was only partially revealed. The price of the stock would have dropped more if the full truth had been disclosed.

3. March 10, 2016 Partial Corrective Disclosure

110. On March 10, 2016, the Company filed its amended annual report for the year ended December 15, 2015 on Form 10-K/A with the SEC. In the "Risk Factors" section, the Company disclosed:

> ***A federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes. The criminal trial is set for some time in 2016. We have received a trial subpoena for documents in connection with that investigation*** and we have been in contact with the U.S. Attorney's Office for the Southern District of Alabama, which is handling the criminal trial, and are cooperating in the production of documents. We are not a target or subject of that investigation. There also have been federal and state investigations of a company that has a product that competes with Abstral in the same therapeutic class, and ***we have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices. On December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral.*** We have been in contact with the U.S. Attorney's Office for the District of New Jersey and are cooperating in the production of the requested documents. We are unable to predict whether we could become subject to legal or administrative actions as a result of these matters, or the impact of such matters. If we are found to be in violation of the False Claims Act, Anti-Kickback Statute, Patient Protection and Affordable Care Act, or any other applicable state or any federal fraud and abuse laws, we may be subject to penalties, such as civil and criminal penalties, damages, fines, or an administrative action of exclusion from government health care reimbursement programs. We can make no assurances as to the time or resources that will need to be devoted to these matters or their outcome, or the impact, if any, that these matters or any resulting legal or administrative proceedings may have on our business or financial condition.
>
> [Emphasis in bold and italics in original.]

111. On this news, the price of Galena common stock fell $0.03 per share, or 3.3%, to close at $0.86 per share on March 11, 2016. This disclosure revealed, for the first time, that "two of the

high-prescribing physicians for Abstral" were then being criminally for prosecuted for "alleged violations of the federal False Claims Act and other federal statutes," and that Galena was at risk of liability for its promotions to those doctors. While revealing some of the true facts and some of the materialized risk associated with Defendants' materially false or misleading statements, the disclosure was only partially corrective. The price of the stock would have dropped more if the full truth had been revealed.

4. May 10, 2016 Partial Corrective Disclosure

112. Then, on May 10, 2016, the Company filed its quarterly report on Form 10-Q with the SEC. Therein, the Company stated:

> A federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes. The criminal trial is set for some time in 2016. We have received a trial subpoena for documents in connection with that investigation and we have been in contact with the U.S. Attorney's Office for the Southern District of Alabama, which is handling the criminal trial, and are cooperating in the production of documents. ***On April 28, 2016, a second superseding indictment was filed in the criminal case, which added additional information about the defendant physicians and provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock.*** To our knowledge, we are a not target or subject of that investigation. There also have been federal and state investigations of a company that has a product that competes with Abstral in the same therapeutic class, and ***we have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices.***
>
> On December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral. We have been in contact with the U.S. Attorney's Office for the District of New Jersey and are cooperating in the production of the requested documents. We are unable to predict whether we could become subject to legal or administrative actions as a result of these matters, or the impact of such matters. If we are found to be in violation of the False Claims Act, Anti-Kickback Statute, Patient Protection and Affordable Care Act, or any other applicable state or any federal fraud and abuse laws, we may be subject to penalties, such as civil and criminal penalties, damages, fines, or an administrative action of exclusion from government health care reimbursement programs. We can make no assurances as to the time or resources that will need to be devoted to these matters or their outcome, or the impact, if any, that these matters or any resulting legal or administrative proceedings may have on our business or financial condition.

[Emphasis added.]

113. On this news Galena's stock price fell $0.10, or 7.2%, to close at $1.38 on May 11, 2016. This disclosure revealed for the first time that "a second superseding indictment was filed in the criminal case, which added additional information about the defendant physicians and provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock," and that Galena "ha[d] learned that the FDA and other governmental agencies *may* be investigating our Abstral promotion practices." While revealing more details about the true facts and some of the materialized risk associated with Defendants' misrepresentations and Galena's exposure to liability, the disclosure was only partially corrective. The price of the stock would have dropped more if the full truth has been revealed.

5. January 9, 2017 Partial Corrective Disclosure

114. On January 9, 2017, the Company filed a Form 8-K with the SEC, which updated Galena's risk disclosures for the year ended December 31, 2015 to disclose that Galena was under criminal investigation by the United States DOJ. The Company disclosed:

> ***Abstral Investigation***
>
> As previously disclosed, on December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office for the District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral, the commercial product we sold in the fourth quarter of 2015. ***We have been in contact with the U.S. Attorney's Office for the District of New Jersey and Department of Justice, and we have come [to] understand that the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and Department of Justice is a criminal investigation in addition to a civil investigation that could ultimately involve the Company as well as one or more current and/or former employees.*** Pursuant to the Company's charter, we are currently reimbursing any former and current employees' attorney's fees with respect to the investigation. We are cooperating with the civil and criminal investigation, and through our outside counsel we have recently begun preliminary discussions with the government aimed at the ultimate resolution of the investigation regarding the Company.
>
> **Update of Risk Factor**

> In light of the disclosure above regarding the Abstral Investigation, the Company is updating the risk factor that appear under the heading "Risks Relating to Our Former Commercial Operations" in all quarterly and annual reports filed under the Securities Exchange Act of 1934, as amended, subsequent to the Company's Annual Report on Form 10-K for the Annual Period Ended December 31, 2015. The following risk factor shall be incorporated by reference into all of the Company's registration statements under the Securities Act of 1933, as amended. Investors in our common stock should carefully consider this risk factor below as well as all other risk factors disclosed in our most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and the other information disclosed by us before making an investment decision.
>
> **Risks Relating to Our Former Commercial Operations**
>
> ***
>
> There also have been federal and state investigations of a company that has a product that competes with Abstral in the same therapeutic class, and ***we have learned that the FDA and other governmental agencies are investigating our Abstral promotion practices***. On December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office for the District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral. We have been in contact with the U.S. Attorney's Office for the District of New Jersey and are cooperating in the production of the requested documents. ***We have come to understand that the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and Department of Justice is a criminal investigation in addition to a civil investigation that could ultimately involve the company as well as one or more current and/or former employees. Pursuant to the Company's charter, we are currently reimbursing any former and current employees' attorney's fees with respect to the investigation.*** We are cooperating with the civil and criminal investigation and through our outside counsel ***we have recently begun preliminary discussions with the government aimed at the ultimate resolution of the investigation regarding the Company***.
>
> [Emphasis added.]

115. On this news, the price of Galena common stock fell $0.04 per share, or 1.9%, to close at $2.03 per share on January 9, 2017. This disclosure revealed for the first time that "the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and Department of Justice is a *criminal* investigation in addition to a civil investigation that could ultimately involve the Company *as well as one or more current and/or former employees*," that Galena had "learned that the FDA and other governmental agencies are investigating our Abstral promotion practices," and that Galena was in preliminary discussions with the government aimed at

the ultimate resolution of the investigation regarding the Company." While revealing even more details about the true facts and some of the materialized risk associated with Defendants material misrepresentations and Galena's exposure to liability, the disclosure was only partially corrective. The price of the stock would have dropped more if the full truth has been revealed.

C. Disclosures at the End of the Class Period

116. Marking the close of the Class Period, on January 31, 2017, the Company announced the resignation of Schwartz as President, CEO, and a member of the Board of Directors, stating:

> SAN RAMON, Calif., Jan. 31, 2017 (GLOBE NEWSWIRE) – Galena Biopharma, Inc. (NASDAQ:GALE), a biopharmaceutical company committed to the development and commercialization of hematology and oncology therapeutics that address unmet medical needs, today announced that the ***Board of Directors has entered into a separation agreement with Mark W. Schwartz, Ph.D. under which Dr. Schwartz will resign from the company*** and its affiliates as the President, Chief Executive Officer, and member of the Board of Directors, ***effective today***. The Board of Directors expects to appoint an Interim Chief Executive Officer in the next couple weeks.
>
> The Board of Directors also announced that it is in the process of engaging an independent advisory firm to evaluate strategic alternatives for the company focused on maximizing stockholder value. Potential strategic alternatives that may be explored or evaluated as part of this review include continuing to advance the clinical programs as a stand-alone entity, a sale of the company, a business combination, merger or reverse merger, and a license or other disposition of corporate assets of the company. There is no set timetable for this process and there can be no assurance that this process will result in a transaction. While the Company evaluates its strategic alternatives, Galena's investigator-sponsored immunotherapy trials will remain ongoing. The Company is evaluating the appropriate time to commence the GALE-401 trial and anticipates making a definitive determination in the second half of 2017.
>
> "After critical assessment of the current status of the company, we believe that it is the right time to run a strategic evaluation of our opportunities as we look to maximize value for our stockholders," said Sanford J. Hillsberg, Galena's Chairman of the Board of Directors. "We acknowledge Mark's six years of service with Galena and wish him well in his future endeavors."

117. A Form 8-K filed with the SEC that same day further provided that "[f]or purposes of Dr. Schwartz' Employment Agreement…, Dr. Schwartz' resignation was without 'Good Reason'."

118. On the same day, January 31, 2017, *TheStreet.com* published an article on Schwartz' resignation. The article titled, "*Galena Sacks CEO Amid Escalating Criminal Probe Into Fentanyl Drug Marketing*," stated, "[t]he timing of Schwartz' exit is noteworthy given Galena's admission on Jan. 9 of a criminal investigation of the company by the U.S. Attorney's Office in New Jersey and the U.S. Department of Justice." As the article explained: "The Feds are investigating Galena's marketing and promotional practices for Abstral, the company's fentanyl-based painkiller, according to an 8-K filing with the Securities and Exchange Commission. ***Schwartz was instrumental in Galena acquiring Abstral in 2013 and played a significant role in the drug's marketing***, according to former employees."

119. Other business and financial writers similarly associated Schwartz's resignation with the pending criminal investigation of Galena and the pending criminal proceeding against Drs. Ruan and Couch. For example, the *San Francisco Business Times* published an article on February 1, 2017 entitled, "Biopharma CEO Exits As Pain Drug Marketing Probe Deepens," which stated that "Galena Biopharma Inc. CEO Mark Schwartz abruptly left his post Tuesday, the company said, as a U.S. Justice Department investigation continues into the marketing of a powerful painkiller drug and the company ponders its future." The article went on to explain: "Federal investigators from the U.S. Attorney's Office in New Jersey and the Department of Justice have been investigating alleged 'pill mills' that prescribe painkillers and have fueled a national painkiller addiction epidemic. Abstral was among drugs prescribed by John Patrick Couch and Xiulus Ruan, co-owners of Physicians' Pain Specialists of Alabama, who have been charged by federal prosecutors with fraud."

120. On this news, the price of Galena common stock fell $0.37 per share, or 22.4%, to close at $1.28 per share on February 1, 2017. The stock price continued to decline, falling another $0.16 per share, or 12.5%, to close at $1.12 on February 2, 2017. These disclosures for the first time implicated Defendant Schwartz, Galena's CEO, in the wrongful promotional practices and provided

further insight into the severity of Galena's wrongful promotional practices and the resulting exposure to liability. These disclosures, in conjunction with the other partially corrective disclosures, sufficiently revealed the material risks that had been concealed by Defendants during the Class Period.

D. Motive

121. Throughout the Class Period, Defendants used Galena's artificially inflated stock to finance its operations. The Company was dependent upon financing to supplement the modest revenues generated from its only salable product, Abstral. As Galena disclosed in its SEC filings, "[i]n the absence of revenue from the commercialization of Abstral, Zuplenz or our product candidates, our potential sources of operational funding are proceeds from the sale of equity and funded research and development payments and payments received under partnership and collaborative agreements."

122. Further, the Company's operating losses had significantly increased during the Class Period. According to Galena's March 5, 2015 earnings press release, operating losses for the year ended December 31, 2014 were $52.2 million compared to an operating loss of $33.8 million for the year ended December 31, 2013. As explained in the press release: "The increase in net operating loss year-over-year is primarily the result of our increased activity and enrollment in our Phase 3 PRESENT trial for NeuVax, our investigator sponsored trials for NeuVax, and our Phase 2 trial for GALE-401, as well as increased selling and marketing expenses associated with the growth of our commercial activities." Because of these increased losses, the Company needed outside financing to maintain its operations and to finance the ongoing clinical trials of its primary drug candidate NeuVax.

123. Thus, on November 18, 2014, the Company entered into a purchase agreement with Lincoln Park Capital, LLC ("LPC") that gave the Company the right to sell to LPC up to $50

million in shares of the Company's common stock over the 36 month term of the purchase agreement. LPC initially purchased 2.5 million shares of Galena common stock. As a result of this initial issuance, the Company received initial net proceeds of $4.9 million. In addition to the LPC's initial purchase of common stock, during 2014, Galena received net proceeds of $8.5 million from LPC's subsequent purchases of a total of 4.6 million shares.

124. During each of the years ended December 31, 2014 and December 31, 2015, respectively, the Company received $2.3 million in net proceeds from the sale of 1.4 million shares of common stock through At Market Issuance Sales Agreements.

125. In March 2015, the Company sold units consisting of common stock and warrants at $1.56 per unit for proceeds of $40.8 million.

126. Each of these financings were possible through, and facilitated by, the artificially inflated stock price. Had Abstral revenues not been inflated through Defendants' undisclosed illegal promotions of Abstral for off-label purposes, through Galena's illegal kickbacks to prescribers, and through the over-prescription of Abstral by at least two doctors who were prescribing for off-label non-medically necessary purposes, the above financings would not have been available. Thus, Defendants were motivated to commit the fraud alleged herein in order to keep the Company's operations ongoing while its product candidates were in clinical development.

127. That Defendants had a specific incentive to issue materially false or misleading information bolsters an inference of scienter based on the other allegations of Defendants' specific knowledge.

VI. CLASS ACTION ALLEGATIONS

128. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that acquired Galena's securities from November 3, 2014 through January 31, 2017, inclusive, and who were

damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

129. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Galena's common stock actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds or thousands of members in the proposed Class. Millions of Galena shares were traded publicly during the Class Period on the NASDAQ. As of October 31, 2016, Galena had 217,019,065 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Galena or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

130. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

131. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

132. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Galena; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

133. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

VII. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

134. The market for Galena's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Galena's securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Galena's securities and market information relating to Galena, and have been damaged thereby.

135. During the Class Period, the artificial inflation of Galena's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint, resulting in the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Galena's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Galena and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant

times, and when disclosed, negatively affected the value of the Company stock. Defendants' materially false and/or misleading statements during the Class Period caused Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

136. At all relevant times, the market for Galena's securities was an efficient market for the following reasons, among others:

(a) Galena stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Galena filed periodic public reports with the SEC and/or the NASDAQ;

(c) Galena regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Galena was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

137. As a result of the foregoing, the market for Galena's securities promptly digested current information regarding Galena from all publicly available sources and reflected such information in Galena's stock price. Under these circumstances, all purchasers of Galena's securities during the Class Period suffered similar injury through their purchase of Galena's securities at artificially inflated prices and a presumption of reliance applies.

VIII. NO SAFE HARBOR

138. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Galena who knew that the statement was false when made.

IX. FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

139. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

140. During the Class Period, Defendants made materially false or misleading statements in the Company's quarterly and annual reports filed with the SEC on Forms 10-Q and 10-K, in other documents filed with the SEC, and in the Company's press releases and/or in the Company's conference calls. Defendants misrepresented material facts or failed to disclose material facts required in order to make the statements they made not materially misleading.

141. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Galena's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Galena and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

142. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

143. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants'

material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Galena's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

144. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Galena's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Galena's securities during the Class Period at artificially high prices and were damaged thereby.

145. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Galena was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Galena securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

146. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

147. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

X. SECOND CLAIM

Violation of Section 20(a) of The Exchange Act
Against Defendant Schwartz

148. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

149. Defendant Schwartz acted as a controlling person of Galena within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of his high-level positions and ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Defendant Schwartz had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendant Schwartz was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

150. In particular, Defendant Schwartz had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

151. As set forth above, Galena and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of his position as a controlling person, Defendants Schwartz is liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendant Schwartz's wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: December 20, 2019

Respectfully submitted,

/s/ William B. Federman

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Liaison Counsel for the Class

CERTIFICATE OF SERVICE

This is to certify that on December 20, 2019, I electronically transmitted this document to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the counsel of record.

/s/ William B. Federman
William B. Federman